DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

MAR 7 2005

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Michiharu Seima
Production Headquarters General Manager
ITO CO. LTD
2091 Arakawa-Hongou, Ami-Chou, Inashiki-gun
Ibaraki-Ken 300-1152
Japan

Dear Mr. Seima:

During an inspection of your firm's main operational office at Tokyo, Japan on May 24, 2004, and factory at Ibaraki-Ken, Japan on May 25, 2004, through May 27, 2004, our investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures various physiotherapy equipment: US-100 Portable Ultrasound Therapy Unit, SW-180 Shortwave Therapy Unit, TM-300 Traction Section, and the Trio-300 Multi-Mode Electrical Stimulator. Your firm has received FDA 510(k) marketing clearance to market these devices in the United States (U.S.). These products are devices under the Federal Food, Drug, and Cosmetic Act (section 201(h) of the Act, (21 U.S.C. § 321(h)) because they are intended for use in the cure, treatment, prevention, or diagnosis of a disease or medical condition, or because they are intended to affect the structure or any function of the body..

The above stated inspection revealed that these medical devices are adulterated within the meaning of Section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, manufacturing, packing, storage, or installation of these devices are not in conformance with the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

Your firm was issued an FDA 483, Notice of Inspectional Observations, at the close of the above referenced inspection. Your firm responded to this notice in a letter to the FDA dated August 31, 2004.

The following are violations of the Quality System regulation observed during the inspection, and we are providing our assessment of the adequacy of each associated response:

1. Failure to validate a process which cannot be fully verified according to established procedures, as required by 21 CFR § 820.75. For example, the firm did not have an adequate validation protocol or results for the soldering and gluing operations.

   Your August 31, 2004, response is not adequate. You state that [redacted] have been established for recording confirmation of validation of production processes. Also, [redacted] and [redacted] have been developed. However, these procedures and work instructions were not submitted. Please submit a copy of these procedures and work instructions for our review.

2. Failure to establish and maintain procedures for implementing corrective and preventive actions, as required by 21 CFR § 820.100(a). For example, the corrective and preventive procedures addressing the analysis of sources of quality data to identify existing and potential causes of nonconforming product or other quality problems were not established. Specifically, [redacted] does not identify or describe the methods that your firm will use to analyze your data sources.

   Your August 31, 2004, response is not adequate. You state that [redacted] have been implemented which identify the data analysis methods to be used. However, this procedure was not submitted. Please submit a copy of this procedure for our review.

3. Failure to adequately establish and maintain process control procedures for production processes, as required by 21 CFR § 820.70. For example, our investigator observed that "black tote style" boxes were used to hold and store printed circuit board (PCB) subassemblies in the production area. Your firm stated that surface resistance testing was performed, presumably of the PCB storage boxes. However, your firm did not establish any procedures and did not document the results of this testing.

   Your August 31, 2004, response is not adequate. You state that management methods for the PCB storage boxes have been established in the [redacted] These methods include procedures for specification of the material quality, timing for implementing inspections, timing for replacement, initial inspection methods, daily inspection methods, periodic inspection methods, and inspection flowcharts. However, these methods and procedures were not submitted. Please submit copies of these methods and procedures for our review.

   In addition, please provide copies of your procedures for electrostatic discharge (ESD) protection of electronic component subassemblies and explain how they address and control the storage conditions and environmental controls for ESD, including use of the "black tote style" boxes that our investigator observed were used to hold and store printed circuit board (PCB) subassemblies in the production area. Please provide copies of the "management methods" or procedures/testing for the containers/boxes used for ESD protection of PCB boards that have been developed and maintained in the [redacted] as described in your August 31, 2004, response.

4. Failure to include, or refer to the location of, the primary identification label and labeling used for each production unit in the device history record (DHR), as required by 21 CFR § 820.184(e). For example, some of the DHRs do not contain copies of the actual labels for each serialized unit. The labels specify the serial number of each product.

   Your August 31, 2004, response is not adequate. You state that [redacted] and [redacted] have been implemented. Please provide a copy of your firm's device history record (DHR) procedure and explain what the specified requirements are for including label information in the DHR. Also, please provide copies of the [redacted] and the [redacted] procedures that were developed and referenced in your August 31, 2004, response for our review.

The above stated inspection also revealed that your devices are misbranded under section 502(t)(2) of the Act (21 U.S.C. 352(t)(2)), in that your firm failed to furnish material or information as required under section 519 of the Act and regulations implementing that section at Title 21 Code of Federal Regulations (21 CFR), Part 806 – Reports of Corrections and Removals. Significant violations include, but are not limited to:

Failure to submit a written report to FDA of a correction or removal initiated by the manufacturer to reduce a risk to health by the device, as required by 21 CFR § 806.10. For example, your firm initiated a software modification in response to [redacted] and other complaints that the traction unit would oscillate with a jerking motion, did not release smoothly, and did not hold the forces programmed into the unit. The [redacted] minimized the "oscillation" and "jerking" motions. Your firm did not submit a written report to FDA that provided information on the correction or removal.

Your August 31, 2004, response is not adequate. You state that a [redacted] and [redacted] have been established. However, this procedure and form were not submitted. Please submit the [redacted] and [redacted] that were developed and referenced in your August 31, 2004, response for our review. In addition, please provide a correction or removal report that provides the following information in accordance with 21 CFR 806 § 10: the registration number of the responsible entity; name, address, and telephone number of the manufacturer or importer; brand name and common name, classification name, or usual name of the device and the intended use of the device; marketing status of the device; model, catalog, or code number of the device and the manufacturing lot or serial number of the device; a description of the event(s) giving rise to the information reported and the corrective or removal actions that have been taken; any illness or injuries that have occurred with use of the device; the total number of devices manufactured or distributed subject to the correction or removal; the date of manufacture or distribution and the device's expiration date or expected life; the names, addresses, and telephone numbers of all domestic and foreign consignees of the devices and the dates and number of devices distributed to each such consignee; and a copy of all communication regarding the correction or removal of all recipients of the communications.

This letter is not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, which may include detaining your devices without physical examination upon entry into the United States until the corrections are completed. Section 801(a) of the Act (21 U.S.C. § 381(a)).

Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the violations including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction should be included with your response to this letter. If the documentation is not in English, please provide an English translation for all information to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement B, Orthopedics, Physical Medicine, and Anesthesiology Devices Branch (OPMAD), 2094 Gaither Road, Rockville, Maryland 20850 USA, to the attention of Bill MacFarland, Chief OPMAD.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to issues that relate to the Quality System Regulation and the Medical Device Reporting Regulation, and does not necessarily address other obligations you have under the Act. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers, International and Consumer Assistance at (800) 638-2041 or through the Internet at http://www.fda.gov.

If you need help in understanding the contents of this letter, please contact Bill MacFarland at the above address or at (240) 276-0120 or FAX (240) 276-0129.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health